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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/820,430

04/08/2004

Charli Kruse

B1180/20026

7174

3000 7590 09/03/2009
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EXAMINER

HAMA, JOANNE

ART UNIT

PAPER NUMBER

1632

NOTIFICATION DATE

DELIVERY MODE

09/03/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@crbcp.com

Office Action Summary	Application No. 10/820,430	Applicant(s) KRUSE, CHARLI	
	Examiner JOANNE HAMA	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,5-14 and 48-86 is/are pending in the application.
- 4a) Of the above claim(s) 14,48-50 and 72-75 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,5-13,51-71 and 76-86 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/26/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 26, 2009 has been entered.

Claims 1, 2, 4, 15-47 are cancelled. Claims 62-86 are new. Per the species election of September 25, 2006, Applicant has elected pancreas (and acinar tissue of pancreas) as the species to be examined. As such, claims 14, 48-50, 72-75, which are not drawn to the elected species, are withdrawn. Further discussion of the withdrawal of these claims is discussed below in Claim Objection.

Claims 3, 5-13, 51-71, 76-86, drawn to a composition consisting of isolated pluripotent adult stem cells obtained from acinar tissue of the pancreas, are under consideration.

Claim Objection

With regard to Applicant's response to the objection of claims 14, 48-50 as being directed to non-elected specification, Applicant requests that this objection be held in abeyance since upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species. In response, to better address this issue,

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the Examiner has withdrawn the claims as being drawn to nonelected invention. All claims that the examiner holds as not being directed to the elected subject matter are withdrawn from further consideration by the examiner in accordance with 37 CFR 1.142(b). See MPEP § 821.01 through § 821.04.

Information Disclosure Statement

Applicant filed an Information Disclosure Statement (IDS) on June 26, 2009. The IDS has been considered.

Withdrawn Rejection

35 USC § 112, Enablement

Applicant's arguments, see pages 7-9 of Applicant's response, filed June 26, 2009, with respect to the rejection of claims 3, 5-14, 48-61 have been fully considered and are persuasive. Applicant provides a declaration from Dr. Kruse, wherein the declaration indicates that pluripotent stem cells can be isolated from pancreatic tissue of goats. In response, this is persuasive and the rejection as it applies to this issue is withdrawn. With regard to the issue of normal karyotype, Applicant indicates that a cytogenetic laboratory indicates that the cells have a normal karyotype. In response, the Examiner had considered this issue and withdrew the rejection as it applied to this issue on January 29, 2009, page 5. With regard to the issue of an ES cell marker, Applicant indicates that the claimed cells are pluripotent and that the term "pluripotent," as used in the specification is defined as equivalent to the "capability to differentiate into

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cells of all 3 germ layers.” In response, this is found persuasive and the requirement to demonstrate that the claimed cell show a characteristic of a pluripotent ES cell is withdrawn. The rejection of claims 3, 5-14, 48-61 has been withdrawn.

New Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3, 5-13, 51-56, 59, 62-71, 76-81, 84 are newly rejected under 35 U.S.C. 102(b) as being anticipated by Clarke et al., 2000, Science, 288: 1660-1663.

Clarke et al. teach isolation of a neural stem cell from the adult mouse brain and that it can give rise to cells of all germ layers (Clarke et al., abstract). With regard to the cells being a purified culture (i.e., a composition consisting of isolated stem cells), Clarke et al. teach that clonal cultures were established (Clarke et al., page 1661, 2nd col., 2nd parag.).

While the instant claims recite a source of the claimed cells, the source provides no structural characteristic that distinguishes stem cells from the brain from stem cells from gastrointestinal tissue and thus, as far as can be told, Clarke et al.'s cells anticipate the claimed invention.

Thus, the claims are rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 5-13, 51-71, 76-86 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Zulewski et al., 2001, Diabetes, 50: 521-533, see IDS, Apte et al., 1998, Gut, 43: 128-133, see IDS, Pittenger et al., 1999, Science, 284: 143-147.

Zulewski et al. teach that nestin-positive cells are in localized regions of the ducts in exocrine acinar tissue in the rat pancreas and that nestin positive cells are mostly devoid of staining for CK19 (a marker of ductal epithelium). Zulewski et al. teach that nestin-positive cells in pancreatic ducts and represent stem cells that have not yet differentiated into a ductal or endocrine phenotype (Zulewski et al., page 528, 1st col., under Nestin expression is also localized within limited focal regions of pancreatic ducts, Figure 6).

While Zulewski et al. teach the identification of nestin-positive cells in ductal cells in acinar tissue of rats, they do not teach that clonal lines were made of the cells.

Apte et al. teach how to obtain cells from the acini of pancreas (Apte et al., page 129, 2nd col. under Isolation and Culture of Pancreatic Stellate Shaped Cells). With regard to obtaining a single cell from a mixture of cells, Pittenger et al. provide this guidance. Pittenger et al. teach that fibroblastic cells that developed into visible

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symmetric colonies 5-7 days after initial plating and that hematopoietic stem cells (HSCs) and nonadherent cells were removed with changes in medium. The isolated cultured mesenchymal cells comprised a single phenotypic population, as determined by flow cytometric analysis (Pittenger et al., page 143, 3rd col., 3rd parag. to page 144, 1st col., 1st parag.).

All of the component parts are taught in Zulewski et al., Apte et al., and Pittenger et al. The only difference is the combination of the "old elements" such that a line of stem cells from pancreatic acinar tissue is obtained. It would have been obvious to an ordinary artisan to make a cell line of the nestin-positive cells in pancreatic acini because Zulewski et al. teach that these cells are stem cells.

Thus, the claims are rejected.

With regard to the cells having particular characteristics (e.g. able to form organoid bodies) (claims 7-13, 55, 65-71, 76, 77, 80), as far as can be told, the cells obtained by the teaching of Zulewski et al., Apte et al., and Pittenger et al. would have these characteristics. Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See *In re Ludtke* 441 F.2d 660, 169 USPQ 563 (CCPA 1971). Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. In

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re Best, Bolton, and Shaw, 195 USPQ 430, 433 (CCPA 1977) citing In re Brown, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

With regard to the claims being drawn to the cells being human (e.g. claim 57), an artisan would have used human pancreatic tissue to obtain nestin-positive cells in order to obtain human stem cells.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Mondays, Tuesdays, Thursdays, and Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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/Joanne Hama/
Primary Examiner
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